Product Jurisdiction & the CBER Ombudsman Function

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What Are We Talking About?

- Product Jurisdiction
  - What is it?
  - Why should I care?
  - Product types
  - Paths to a jurisdiction decision
- CBER Ombudsman Function
  - What is it?
  - How does it work?
  - Types of inquiries

What is Product Jurisdiction?

- Determination of which Center or agency component* within FDA is assigned primary responsibility for review and regulation of a product.
- Other questions that may be asked
  - What is it?
  - If it is a joint review how will the centers interact?
  - What regulatory authorities will be applied?

* Language from MDUFMA

Why ask?

- Early product development program
- Business decisions and long term planning

When Do You Need to Ask?

- New technology introduced
- Old technologies combined in a new form
- Precedents for other (related) products appear to be inconsistent
- Any time there is uncertainty
- As soon as possible

General Product Categories

- Novel single entity products
- Combinations
  - Novel drug/biologic delivery systems
  - Integrated biologic/device systems intended for:
    - Metabolic support
    - Tissue repair,regeneration, replacement

Novel Single Entity Products

- One primary component (single entity product)
  - Intercenter agreements
    - New technologies may not be discussed
    - Doesn’t reflect recent product transfers
  - Guidance documents
  - Informal input from center jurisdiction officers
  - RFD process

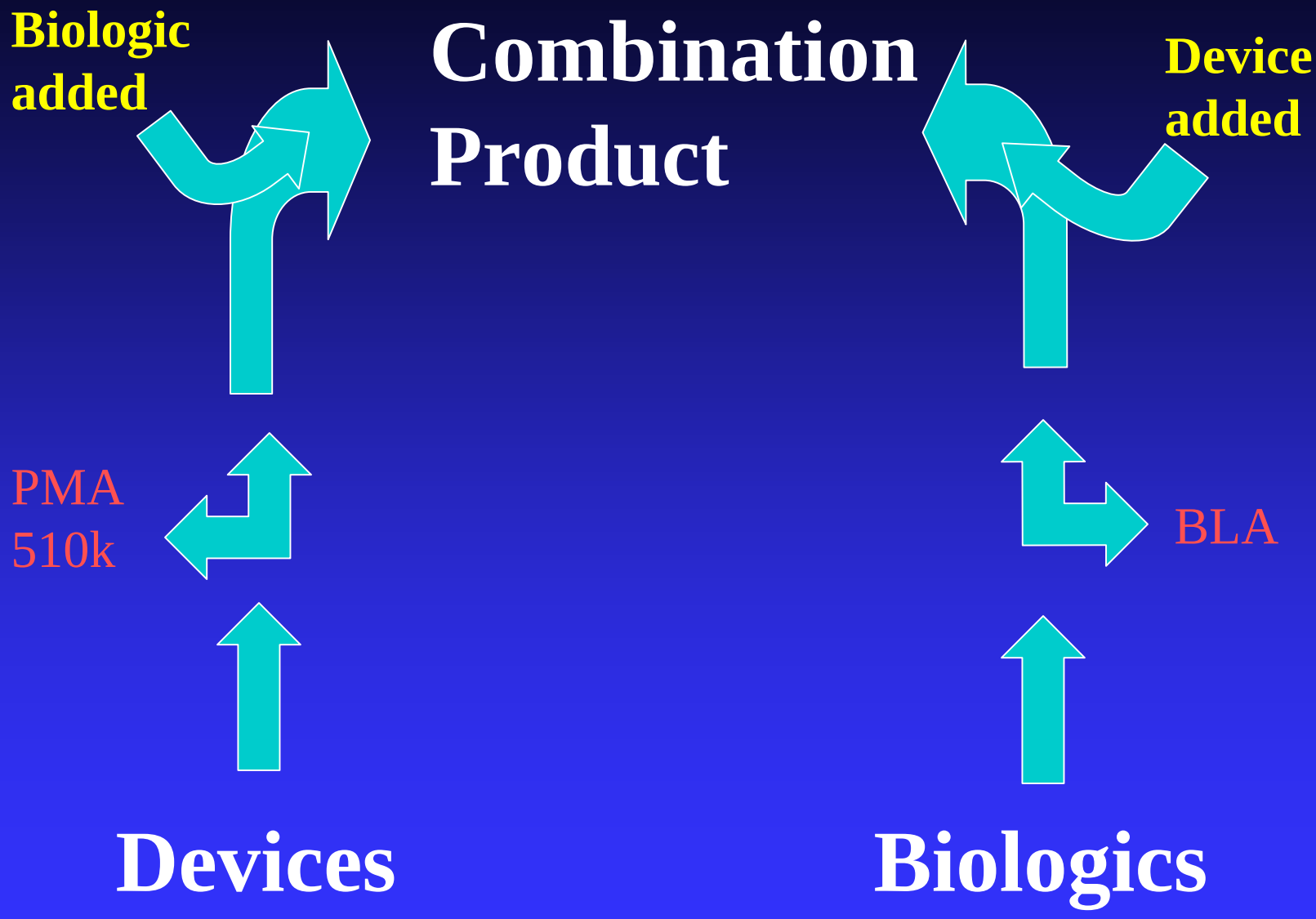
Combination Products - Defined

- 21 CFR 3.2 (e)1: “A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity”

- 21 CRF 3.2(e)2-4

Tricky Combinations

- Novel combinations
  - Emerging technologies
  - New twists on old products
- Appropriate assignment may not be obvious.


Biologic added
Combination Product
Device added
PMA 510k
BLA
Devices
Biologics

How Jurisdictional Decisions Are Made for Combinations

- For Combinations: Primary mechanism of action (21 CFR 3.4)
  - "To designate the agency component with primary jurisdiction for the premarket review and regulation of a combination product, the agency shall determine the primary mode of action of the product."

Combination Product Decisions

- Mechanism of action inconclusive… So now what?
- Other factors that have been be considered:
  - Center expertise with most complex safety and/or efficacy issues
  - Assignment of very closely related products
  - Center expertise with specific product categories
  - Unique regulatory requirements

Review of Combination Products

- **Lead Center**
  - **responsible for taking action**
  - **one focal point for sponsor/agency interaction**
  - **option for consult or collaborative review**

Other Relevant Questions

- Which regulatory authorities will apply?
  - Biologic, drug or device?
  - One application or two?
  - Mixing regulatory authorities
- Joint review: How will the two centers interact?
  - Consult
  - Collaboration
  - Two applications/shared responsibility

Questions about Jurisdiction?

- CBER: Call the CBER Ombudsman (301-827-0379)
- CDER: Call the CDER Ombudsman (301-594-5443)
- CDRH: Call the CDRH Chief Jurisdictional Officer (301-594-1190, ext 132)
- Intercenter issues: Call the FDA Office of Combination Products (301-827-9229)

What Is an Ombudsman?

CBER Ombudsman

- Impartial
- Independent
- Informal
- Confidential

CBER's Ombudsman Function

- External Ombudsman:
  - Deals with industry/sponsor disputes with CBER
    - formal
    - informal
  - Common Problems
    - Scientific Assessment
    - Regulatory Assessment
    - Process Issues

Ombudsman Function

- Improve Communication:
  - identify level of organization where “block” exists
  - identify circumstance(s) of disagreement
  - talk to supervisor
  - identify next level
  - mediate/facilitate further discussion

Formal Vs. Informal Disputes

- **Formal**
  - FDAMA (§404)
  - formal timelines
  - formal response
  - records: all detailed information retained
- **Informal**
  - informal mechanism
  - no set timelines
  - informal response/agreements
  - records: only general information kept in Ombudsman file

CBER Informal Disputes

- Approximately 89 ombudsman contacts or requests for intervention were received in FY-03 from 10/2/2002 through 2/24/2004. Of these, 12 were considered to be major interventions.

CBER Informal Disputes

- 89 contacts related to a variety of issues:
  - 33 scientific, regulatory or process disputes
  - 20 jurisdiction decisions
  - 15 high-level policy issues
  - 1 FOI issues
  - 8 compliance issues
  - 12 “other”

CBER Formal Disputes

- Only 5 formal disputes (7 goal dates) filed with CBER in the last four years (none in FY 2003 or 2004):
  - 3 did not proceed beyond the first cycle
  - 2 Completed
    - 1 product, 2 cycles: resolved as requested by the sponsor
    - 1 product, 2 cycles: compromise reached

How to Contact the CBER Ombudsman

CBER Ombudsman – Sheryl Lard Whiteford

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